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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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TAROLLI, SUNDHEIM, COVELL & TUMMINO L.L.P.
1300 EAST NINTH STREET, SUITE 1700
CLEVEVLAND, OH 44114

| EXAMINER | |
|---|---|
| SGAGIAS, MAGDALENE K | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1632 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/565,616 | UPTON ET AL. | |
| | Examiner | Art Unit | |
| | MAGDALENE K. SGAGIAS | 1632 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *24 January 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-36* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

**DETAILED ACTION**

Claims 1-36 are pending.

***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) **1-23,** drawn to a mammalian cell culture medium comprising: (i) at least one IGF selected from IGF-I and IGF-II; (ii) vitronectin (VN) or a fragment thereof; and (iii) an absence of serum or an amount of serum which in the absence of said at least an IGF would not support cell growth.

Group II, claim(s) **24-28**, drawn to a method of cell culture including the step of culturing one or more cells in the mammalian cell culture system, wherein a mammalian cell culture system comprising a culture vessel and the mammalian culture medium, wherein a mammalian cell culture medium comprising: (i) at least one IGF selected from IGF-I and IGF-II; (ii) vitronectin (VN) or a fragment thereof; and (iii) an absence of serum or an amount of serum which in the absence of said at least an IGF would not support cell growth.

Group III, claim(s) **29-34,** drawn to a pharmaceutical composition for aerosol delivery of keratinocytes or keratinocyte progenitor cells comprising one or more keratinocytes cultured according to the method of, wherein a method of cell culture including the step of culturing one or more cells in the mammalian cell culture system, wherein a mammalian cell culture system comprising a culture vessel and the mammalian culture medium, wherein a mammalian cell culture medium comprising: (i) at least one IGF selected from IGF-I and IGF-II; (ii) vitronectin (VN) or a fragment thereof; and (iii) an absence of serum or an amount of serum which in the absence of said at least an IGF would not support cell growth, together with a pharmaceutically acceptable carrier, diluent or excipient, wherein a pharmaceutical composition for aerosol delivery of keratinocytes.

Group IV, claim(s) **29-34,** drawn to a pharmaceutical composition for aerosol delivery of keratinocytes or keratinocyte progenitor cells comprising one or more keratinocytes cultured according to the method of, wherein a method of cell culture including the step of culturing one or more cells in the mammalian cell culture system, wherein a mammalian cell culture system comprising a culture vessel and the mammalian culture medium, wherein a mammalian cell culture medium comprising: (i) at least one IGF selected from IGF-I and IGF-II; (ii) vitronectin (VN) or a fragment thereof; and (iii) an absence of serum or an amount of serum which in the absence of said at least an IGF would not support cell growth, together with a pharmaceutically

acceptable carrier, diluent or excipient, wherein a pharmaceutical composition for aerosol delivery of keratinocyte progenitor cells.

Group VI, claim(s) **35-36**, drawn to a method of delivering keratinocytes or keratinocyte progenitor cells for skin regeneration in situ including the step of spraying the pharmaceutical composition of any pharmaceutical composition for aerosol delivery of keratinocytes or keratinocyte progenitor cells comprising one or more keratinocytes cultured according to the method of a method of cell culture including the step of culturing one or more cells in the mammalian cell culture system, wherein a mammalian cell culture system comprising a culture vessel and the mammalian culture medium, wherein a mammalian cell culture medium comprising: (i) at least one IGF selected from IGF-I and IGF-II; (ii) vitronectin (VN) or a fragment thereof; and (iii) an absence of serum or an amount of serum which in the absence of said at least an IGF would not support cell growth, together with a pharmaceutically acceptable carrier, diluent or excipient, onto the skin of an individual to facilitate skin regeneration, wherein a pharmaceutical composition for aerosol delivery of keratinocytes.

Group VII, claim(s) **35-36**, drawn to a method of delivering keratinocytes or keratinocyte progenitor cells for skin regeneration in situ including the step of spraying the pharmaceutical composition of any pharmaceutical composition for aerosol delivery of keratinocytes or keratinocyte progenitor cells comprising one or more keratinocytes cultured according to the method of a method of cell culture including the step of culturing one or more cells in the mammalian cell culture system, wherein a mammalian cell culture system comprising a culture vessel and the mammalian culture medium, wherein a mammalian cell culture medium comprising: (i) at least one IGF selected from IGF-I and IGF-II; (ii) vitronectin (VN) or a fragment thereof; and (iii) an absence of serum or an amount of serum which in the absence of said at least an IGF would not support cell growth, together with a pharmaceutically acceptable carrier, diluent or excipient, onto the skin of an individual to facilitate skin regeneration, wherein a pharmaceutical composition for aerosol delivery of keratinocyte progenitor cells.

The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: **Upton et al** [WO 02/24219 (IDS)] discloses a mammalian cell culture system comprising (i) IGF-I and IGF-II; (ii) vitronectin; and an amount of serum for cell growth support (abstract and throughout the document). Thus, the technical feature of IGF, vitronectin and serum is not special and the groups are not so linked under PCT Rule 13.1.

1. Claims 8 and 33 and their dependant claims contain different IGFBP selected from the group consisting of IGFBP1, IGFBP2, IGFBP3, IGFBP4, IGFBP5 and IGFBP6. Applicant is advised to **elect only one** said IGFBP even though this is not an election of species

it is a restriction requirement, because each IGFBP requires distinct structural components resulting in distinct culture effects.

2. Claim 14 contains different avbeta3 integrin or an avbeta5 integrin. Applicant is advised to **elect only one** said integrins even though this is not an election of species it is a restriction requirement, because each integrin requires distinct structural components resulting in distinct culture effects.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double

patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAGDALENE K. SGAGIAS whose telephone number is (571)272-3305. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paras Peter can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Anne-Marie Falk/
Anne-Marie Falk, Ph.D.
Primary Examiner, Art Unit 1632